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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/773,736	02/02/2001	Hirokazu Kubota	Q62542	6936
7590	09/18/2002			
SUGHRUE, MION, ZINN MACPEAK & SEAS, PLLC 2100 Pennsylvania Avenue, N.W. Washington, DC 20037			EXAMINER RAO, DEEPAK R	
			ART UNIT 1624	PAPER NUMBER 8
			DATE MAILED: 09/18/2002	

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

	Application No. <b>09/773,736</b>	Applicant(s) <b>Kubota et al.</b>
	Examiner <b>Deepak Rao</b>	Art Unit <b>1624</b>



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Jul 8, 2002.

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-43 is/are pending in the application.

4a) Of the above, claim(s) 8, 9, 18, and 19 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-7, 10-17, and 20-43 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2, 4 & 5

6)  Other:

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## DETAILED ACTION

Claims 1-43 are pending in this application.

### *Election/Restriction*

Applicant's election of the species of Example 1, 4'-[3,5-bis(trifluoromethyl)-1H-pyrazol-1-yl]-4-methylthiazole-5-carboxamilide in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The elected species represents a compound of formula (I) wherein:

D is 1H-pyrazol-1-yl;

n is 0;

B is 1,4-phenylene;

X is -NH-CO-; and

A is 4-methylthiazol-5-yl.

Applicant is reminded of the election of species guidelines provided in MPEP § 803.02, which are followed for examination. Portion of MPEP section is provided here for convenience:

As an example, in the case of an application with a Markush-type claim drawn to the compound C-R, wherein R is a radical selected from the group consisting of A, B, C, D and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD or CE. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the non-elected species would be held withdrawn from further

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consideration. As in the prevailing practice, a second action on the merits on the elected claims would be final.

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

The elected species was not found in the prior art search and the search was expanded to other values of A while maintaining the definitions of D, n, B and X as listed above, and art was found.

As per the guidelines above, claims 8, 18 (drawn to compounds of formula (I) wherein D is 1-methyl-3-trifluoromethyl-1H-pyrazol-5-yl) and claims 9, 19 (drawn to compounds wherein A is monocyclic heteroaryl) and the generic subject matter of the remaining claims, other than the above groups is withdrawn from consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species.

#### *Claim Rejections - 35 U.S.C. § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-7, 10-17 and 20-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. In the claims, the term “derivative” (all occurrences) adjacent to ‘pyrazole’ is open ended. This term would allow for groups other than those recited in the claim. Replacing the above recitation with -- compound -- (in all occurrences) is suggested.
2. In claim 1, in the definition of D, in the substituent list, the term “-halogeno-lower alkyl” is confusing because it appears that the point of attachment is through ‘halogen’ which is not possible because halogen is a monovalent group. Replacing the term with ‘halogeno-lower alkyl-’ is suggested. The same discrepancy appears in claims 4, 10, 21 and 26-29.
3. Claim 1 recites the limitation "Y is NHCO" in lines 2 and 4 on page 6 (see the proviso statements (4) and (5)). There is insufficient antecedent basis for this limitation in the claim. There is no variable “ Y ” in the claim.
4. In claim 10, there is no recitation of an “pharmaceutically effective amount” of the compound. Since the claim is drawn to a pharmaceutical composition, appropriate effective amount should be recited.

The other claims are included here because they are dependent claims and do not resolve the issue.

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***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Finar et al., Chem. Abstract 55:25921f. The instantly claimed compounds read on the reference disclosed compound, see the compound of RN 99990-41-7 in enclosed copy of CAOLD computer search report.
2. Claims 1-4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Bouchet et al., Chem. Abstract 85:5545. The instantly claimed compounds read on the reference disclosed compounds, see RN 59352-27-1 and 59352-30-6 disclosed in CAPLUS computer search report.
3. Claims 1-4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al., WO 85/04878. The instantly claimed compounds read on the reference disclosed compound, see the compound (c) under Example 3 (page 39, lines 7-8).
4. Claims 1-4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Campbell et al., U.S. Patent No. 4,728,653. The instantly claimed compounds read on reference disclosed compounds, see compound of Preparation No. 11 (col. 35) and Preparation No. 28 (col. 41).

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5. Claims 1-4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Mizukawa et al., JP 010055557. The instantly claimed compounds read on the reference disclosed compound, see RN 123607-09-0 in the enclosed copy of CAPLUS computer search report (111:205323).

6. Claims 1-4, 7, 10-14 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Patel et al., Chem. Abstract 114: 23862. The instantly claimed compounds read on the compounds of the reference, see the compounds disclosed in the enclosed copy of CAPLUS computer search report, e.g., the compound RN 131138-68-6, 131138-55-1, etc.

7. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Petersen et al., WO 96/31517. The instantly claimed compounds read on the reference disclosed compounds, see the compounds in Table 3, e.g., the first compound wherein T = O; R<sup>3</sup> = H; n = 0; XR<sup>1</sup> = CH(CH<sub>3</sub>)<sub>2</sub>; R<sup>2</sup> = CH<sub>3</sub>; and R<sup>4</sup> = CF<sub>3</sub>.

8. Claims 1-7 and 30 are rejected under 35 U.S.C. 102(a) as being anticipated by Kawamura et al., JP 10072434 (published March 17, 1998). The instantly claimed compounds read on the reference compounds, see the compounds disclosed in the enclosed copy of CAPLUS computer search report (128:230375), e.g., RN 204516-89-2.

**Note:** Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

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***Duplicate Claims***

Applicant is advised that should claim 10 be found allowable, claims 11-14 and 20 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, claims 11-14 and 20 recite an intended use of the composition without setting forth any positive steps or limitations and accordingly, they are substantial duplicates of claim 10.

***Allowable Subject Matter***

Claim 37 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, (see reason no. 1) set forth in this Office action.

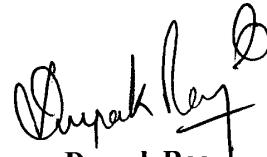
Claims 15-16, 21-29, 31-36 and 38-43 would be allowable if rewritten or amended limiting the scope to the elected/examined invention (as indicated above) and to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Receipt is acknowledged of the Information Disclosure Statements filed on February 2, 2001; February 6, 2002 and March 6, 2002 and copies are enclosed herewith. Receipt is acknowledged of the International Search Report and the cited references are considered.

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Deepak Rao  
Primary Examiner  
Art Unit 1624

September 17, 2002